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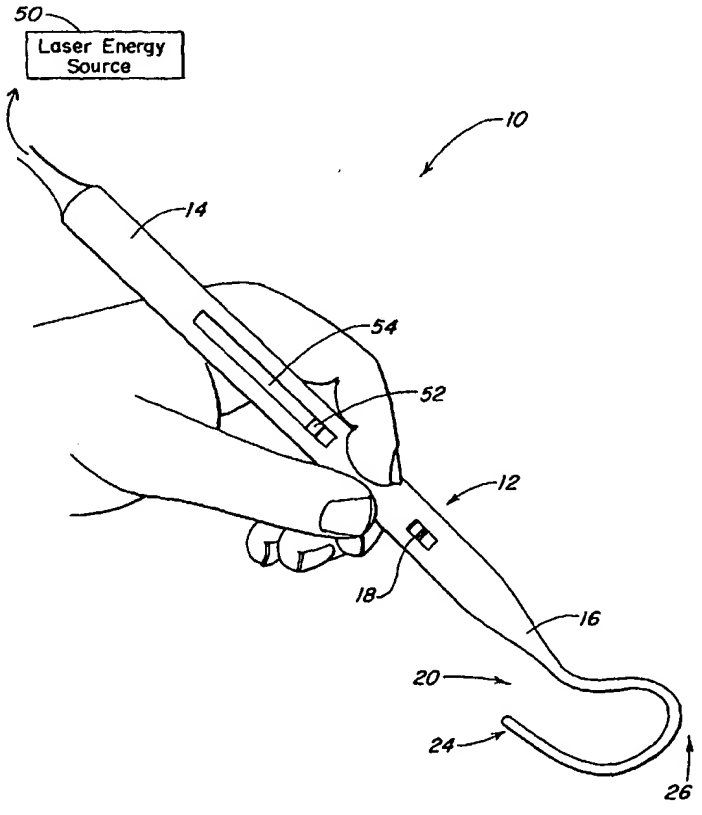

(57) Abstract: Photoablation instruments are disclosed for creating lesions in tissue, especially cardiac tissue for treatment of arrhythmias and the like. The hand held instruments are especially useful in open chest or port access cardiac surgery for rapid and efficient creation of curvilinear lesions to serve as conduction blocks. The instruments can be used to form either endocardial or epicardial ablations, and are designed to create lesions in the atrial tissue using radiant energy in order to electrically decouple tissue segments on opposite sides of the lesion. The instrument can include a light delivering element having a light transmitting optical fiber and alight diffusing element. The light delivering element can be disposed within a pre-shaped or malleable housing to create a curvilinear lesion. The light diffusing element provides a substantially uniform distribution of laser radiation to the circular target region in an elongated curvilinear pattern. Methods of use are also provided.

WO 02/05722 A1

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CARDIAC PHOTOABLATION INSTRUMENTS

Background of the Invention

The present invention relates to cardiac ablation instruments for endocardial or epicardial ablation of tissue for the treatment of cardiac conditions, and, in particular, to handheld cardiac photoablation instruments which provide uniform radiation. Methods of ablating cardiac tissue using radiant energy are also disclosed.

Cardiac rhythm irregularities, e.g., fibrillation, are pathological conditions of the heart muscle that can be present in either the atria or the ventricles. For example, atrial fibrillation is a form of arrhythmia characterized by rapid randomized contractions of the atrial myocardium, causing an irregular, often rapid ventricular rate. The regular pumping function of the atria is replaced by a disorganized, ineffective quivering as a result of chaotic conduction of electrical signals through the upper chambers of the heart. Atrial fibrillation is often associated with other forms of cardiovascular disease, including congestive heart failure, rheumatic heart disease, coronary artery disease, left ventricular hypertrophy, cardiomyopathy or hypertension.

Various surgical techniques have been proposed for the treatment of arrhythmia. By ablating the heart tissue (typically in the form linear or curved lesions) at selected locations, electrical conductivity from one segment to another can be blocked and the resulting segments become too small to sustain the fibrillatory process on their own. Ablation procedures are often performed during coronary artery bypass and mitrial valve replacement operations because of a heightened risk of arrhythmias in such patients and the opportunity that such surgery presents for direct access to the heart.

Although these procedures were originally performed with a scalpel, several other types of ablation devices have recently been proposed for creating lesions to treat cardiac arrhythmias, including devices which employ electrical current heating or cryogenic cooling. Such ablation devices have been proposed to create elongated lesions that extend through a sufficient thickness of the myocardium to block electrical conduction.

These devices, however, are not without their drawbacks. Because these devices rely upon resistive or conductive heating (or cooling), they must be placed in direct contact with the heart and such contact must be maintained for a considerable period of time to form a lesion that extends through the entire thickness of the heart muscle. This is particularly problematic for procedures that are performed upon a "beating heart" patient. In such cases the heart, itself, continues to beat and, hence, is filled with blood, thus providing a heat sink (or reservoir) that works against conductive and/or resistive ablation devices. As "beating heart" procedures become more commonplace (in order to avoid the problems associated with arresting a patient's heart and placing the patient on a pump), the need for better ablation devices will continue to grow.

Moreover, when cardiac surgery is performed "on pump," the amount of time necessary to form a lesion becomes a critical factor. Again, devices that rely upon resistive or conductive heat transfer suffer serious drawbacks. In order to quickly perform an ablation with such "contact" devices, a significant amount of energy must be applied directly to the target tissue site. In order to achieve transmural penetration, the surface that is contacted will experience a greater degree of heating (or freezing). Charring or cryo-destruction of heart tissue can lead to post-operative complications, such as damage to surrounding nerves and blood vessels of the heart or the pericardium. Even if structural damage is avoided, the extent of the lesion (i.e., the width of the ablated zone) on the surface that has been contacted will typically be greater than necessary.

Ablation devices that do not require direct contact have also been proposed, including acoustic, microwave and photonic sources of radiant energy. Acoustic energy (e.g., ultrasound) is poorly transmitted into tissue (unless a coupling fluid is interposed). Microwave devices have been proposed, but are generally unwieldy because of difficulties in directing such radiation and achieving uniformity. Laser energy has also been proposed but only in the context of devices that focus light into spots or other patterns. When the light energy is delivered in the form of a focused spot, the process is inherently time consuming because of the need to expose numerous spots to form a continuous linear or curved lesion.

Accordingly, there exists a need for better cardiac ablation instruments that can form lesions with minimal overheating and/or damage to collateral tissue. Moreover, instruments that are capable of creating lesions uniformly, rapidly and efficiently would satisfy a significant need in the art.

Summary of the Invention

Photoablation instruments are disclosed for creating lesions in tissue, especially cardiac tissue for treatment of arrhythmias and the like. The hand held instruments are especially useful in open chest or port access cardiac surgery for rapid and efficient creation of curvilinear lesions to serve as conduction blocks. The instruments can be applied to form either endocardial or epicardial ablations, and are designed to create lesions in the atrial tissue in order to electrically decouple tissue segments on opposite sides of the lesion.

The instruments of the present invention can achieve rapid and effective photoablation through the use of distributed radiant energy. It has been discovered that distributed radiant energy, e.g., diffuse infrared radiation, can create lesions in less time and with less risk of the adverse types of tissue destruction commonly associated with prior art approaches. Unlike instruments that rely on thermal conduction or resistive heating, controlled radiant energy can be used to simultaneously deposit energy throughout the full thickness of a target tissue, such a heart wall, even when the heart is filled with blood. Distributed radiant energy can also produce better defined and more uniform lesions.

It has also been discovered that infrared radiation is particularly useful in forming photoablative lesions. In one preferred embodiment the instruments emit radiation at a wavelength in a range from about 800 nm to about 1000 nm, and preferably emit at a wavelength in a range of about 915 nm to about 980 nm. Radiation at a wavelength of 915 nm or 980 nm is commonly preferred, in some applications, because of the optimal absorption of infrared radiation by cardiac tissue at these wavelengths. In the case of ablative radiation that is directed towards the epicardial surface, light at a wavelength about 915 nm can be particularly preferably.

In one aspect of the invention, surgical ablation instruments are disclosed having a housing with at least one lumen therein and having a distal portion that is at least partially transmissive to photoablative radiation. The instruments further include a light delivery element within the lumen of the housing that is adapted to receive radiation from a source and delivery radiant energy through a transmissive region of the housing to a target tissue site. The radiant energy is delivered without the need for contact between the light emitting element and the target tissue because the instruments of the present invention do not rely upon conductive or resistive heating.

The distal end of the instrument can have a malleable shape or be in the shape of an open loop so as to allow the loop to be placed around at least one a pulmonary vein or artery and, optionally, the distal end of housing can be shaped into a loop having a diameter between about 10 and 50 mm. Moreover, the instrument can further include at least one malleable strip element disposed with the distal end of the housing so that the distal end can be conformed into a desired shape. In addition, the instrument can also include a clasp for closing the loop after encircling at least one pulmonary vein.

The light delivering element can be a light transmitting optical fiber adapted to receive ablative radiation from a radiation source and a light emitting tip at a distal end of the fiber for emitting diffuse or defocused radiation. The light delivering element can be slidably disposed within the inner lumen of the housing and the instrument can further include a translatory mechanism for disposing the tip of the light delivering element at one or more of a plurality of locations with the housing. Optionally, a lubricating fluid can be disposable between the light delivery element and the housing. This fluid can be a physiologically compatible fluid, such as saline, and the fluid can also be used for cooling the light emitting element or for irrigation via one or more exit ports in the housing.

The light emitting tip can include a hollow tube having a proximal end joined to the light transmitting optical fiber, a closed distal end, and an inner space defining a chamber therebetween. The light scattering medium disposed within the chamber can be a polymeric or liquid material having light scattering particles, such as alumina, silica, or titania compounds or mixtures thereof, incorporated therein. The distal end of the tube can include a reflective end and, optionally, the scattering medium and the

reflective end can interact to provide a substantially uniform axial distribution of radiation over the length of the housing.

Alternatively, the light emitting tip can include at least one reflector for directing the radiation through the transmissive region of the housing toward a target site and, optionally can further include a plurality of reflectors and/or at least one defocusing lens for distributing the radiation in an elongated pattern.

The light emitting tip can further include at least one longitudinal reflector or similar optical element such that the radiation distributed by the tip is confined to desired angular distribution.

The hand held instruments can include a handle incorporated into the housing. An inner lumen can extend through the handle to received the light delivering element. The distal end of the instrument can be resiliently deformable or malleable to allow the shape of the ablation element to be adjusted based on the intended use.

In one embodiment, a hand held cardiac ablation instrument is provided having a housing with a curved shape and at least one lumen therein. A light delivering element is disposable within the lumen of the housing for delivering ablative radiation to form a curved lesion at a target tissue site adjacent to the housing.

In another aspect of the invention, the light delivering element can be slidably disposed within the inner lumen of the housing, and can include a light transmitting optical fiber adapted to receive ablative radiation from a radiation source and a light diffusing tip at a distal end of the fiber for emitting radiation. The instrument can optionally include a handle joined to the housing and having an inner lumen though which the light delivering element can pass from the radiation source to the housing.

In another aspect of the present invention, the light diffusing tip can include a tube having a proximal end mated to the light transmitting optical fiber, a closed distal end, and an inner chamber defined therebetween. A light scattering medium is disposed within the inner chamber of the tube. The distal end of the tube can include a reflective end surface, such as a mirror or gold coated surface. The tube can also include a curved, longitudinally-extending, reflector that directs the radiant energy towards the target ablation site. The reflective surfaces and the light scattering medium interact to provide a substantially uniform axial distribution of radiation of the length of the housing.

In other aspects of the present invention, a hand held cardiac ablation instrument is provided having a slidably disposed light transmitting optical fiber, a housing in the shape of an open loop and having a first end adapted to receive the slidably disposed light transmitting optical fiber, and at least one diffuser chamber coupled to the fiber and disposed within the housing. The diffuser chamber can include a light scattering medium disposed within the housing and coupled to the slidably disposed light transmitting optical fiber.

The present invention also provides methods for ablating cardiac tissue. One method of ablating cardiac tissue, comprises positioning a distal end of a photoablation instrument in proximity to a target region of cardiac tissue, the instrument having a hollow housing and a light delivering element coupled to a source of photoablative radiation and disposed within the distal end, the distal end being transmissive to a selected wavelength of ablative radiation and curved to permit the distribution of radiation by the light emitting element in an elongated arcuate pattern; activating the light emitting element to transmit radiant energy through the housing to expose the target region and induce an curvilinear lesion; and, optionally, repeating the steps of positioning and exposing until a composite lesion of a desired shape is formed.

In another method, a device is provided having a light delivering element coupled to a source of photoablative radiation and configured in a curved shape to emit an arcuate pattern of radiation. The device is positioned in proximity to a target region of cardiac tissue, and applied to induce a curvilinear lesion. The device is then moved to the second position and reapplied to induce a second curvilinear lesion. The steps of positioning and reapplying can be repeated until the lesions are joined together to create a composite lesion (e.g., a closed loop encircling one or more cardiac structures).

In another embodiment, a methods of ablating cardiac tissue are provided. A device is provided having a housing in the shape of a hollow ring or partial ring having at least one lumen therein and at least one open end, and a light delivering element slidably disposed within the lumen of the housing for delivering ablative radiation to form a circular lesion at a target region adjacent the housing. The methods includes the steps of positioning the device in proximity to the target region of cardiac tissue, applying the device to the target region to induce a curvilinear lesion, advancing the light delivering element to a second position, reapplying the device to the target region

to induce a second curvilinear lesion, and repeating the steps of advancing and applying until the lesions are joined together to create a composite circumferential lesion.

Brief Description of the Drawings

The invention will be more fully understood from the following detailed description taken in conjunction with the accompanying drawings, in which like reference numerals designate like parts throughout the figures, and wherein:

FIG. 1 is a schematic, perspective view of a hand held surgical ablation instrument in accordance with this invention;

FIG. 1A is a partially cross-sectional view of the hand held surgical ablation instrument of FIG. 1;

FIG. 2 is a schematic, perspective view of another embodiment of a hand held surgical ablation instrument in accordance with this invention;

FIG. 2A is a partially cross-sectional view of the hand held surgical ablation instrument of FIG. 2;

FIG. 3 is a schematic, side perspective view of a tip portion of an ablation instrument in accordance with this invention illustrating a light delivery element;

FIG. 3A is a schematic, side perspective view of a tip portion of another ablation instrument in accordance with this invention;

FIG. 4 is a schematic, cross sectional view of the light delivery element of FIG. 3;

FIG. 4A is a schematic, cross sectional view of another embodiment of a light delivery element;

FIG. 4B is a schematic, cross sectional view of another embodiment of a light delivery element surrounded by a malleable housing;

FIG. 5 is a schematic, cross sectional top view of a surgical ablation element of according to the invention, illustrating the different ablating positions of the light delivering element; and

FIG. 6 is a schematic, perspective view of a human heart and an instrument according to the invention, showing one technique for creating epicardial lesions.

FIG. 7 is a schematic, perspective view of a human heart and an instrument according to the invention, showing one technique for creating endocardial lesions.

FIG. 8 is a schematic, perspective view of a human heart and an instrument according to the invention, showing another technique for creating endocardial lesions.

Detailed Description

The present invention provides a hand held cardiac ablation instrument that is useful for treating patients with atrial arrhythmia. As shown in FIG. 1, the hand held cardiac ablation instrument 10 generally includes a handle 12 having a proximal end 14 and a distal end 16, an ablation element 20 mated to or extending distally from the distal end 16 of the handle 12, and a laser energy source 50. The laser energy source 50 employs the use of electromagnetic radiation, e.g., coherent light, which can be efficiently and uniformly distributed to the target site while avoiding harm or damage to surrounding tissue. In use, the instrument can be applied either endocardially or epicardially, and is effective to uniformly irradiate a target ablation site.

The handle 12 of the cardiac ablation instrument 10 is effective for manually placing the ablation element 20 proximate to a target tissue site. While the handle 12 can have a variety of shapes and sizes, preferably the handle is generally elongate with at least one inner lumen extending therethrough. The proximal end 14 of the handle 12 is adapted for coupling with a source of phototherapeutic radiation, i.e. a laser energy source 50, and the distal end of the handle 16 is mated to or formed integrally with the ablation element 20. In a preferred embodiment, the handle 12 is positioned substantially coaxial with the center of the ablation element 20. The handle 14 can optionally include an on-off switch 18 for activating the laser energy source 50.

One circumferential ablation element 20 is shown in more detail in FIG. 1A, and includes an outer housing 22 having an inner lumen extending therethrough, and a light delivering element 32 disposed within the inner lumen of the outer housing 22. The outer housing 22 can be flexible, and is preferably malleable to allow the shape of the outer housing 22 to be adapted based on the intended use. As shown in FIG. 2, the outer housing 22 can be in the shape of a hollow ring (or partial ring) forming an opening loop having leading and trailing ends 24, 26. The open loop-shape allows the circumferential ablation element 20 to be positioned around one or more pulmonary veins. While an open loop shape is illustrated, the outer housing 22 can also be formed or positioned to create linear or other shaped lesions.

The housing can be made from a variety of materials including polymeric, electrically nonconductive material, like polyethylene or polyurethane, which can withstand tissue coagulation temperatures without melting. Preferably, the housing is made of Teflon® tubes and/or coatings. The use of Teflon® improves the procedures by avoiding the problem of fusion or contact-adhesion between the ablation element 12 and the cardiac tissue during usage. While the use of Teflon® avoids the problem of fusion or contact-adhesion, the hand held cardiac ablation instrument 10 does not require direct contact with the tissue to effect a therapeutic or prophylactic treatment.

The outer housing 22 can optionally include a connecting element for forming a closed-loop circumferential ablation element 20. By non-limiting example, FIG. 1A illustrates a connecting element 30 extending from the leading, distal end 24 of the outer housing 22. The connecting element 30 has a substantially u-shape and is adapted for mating with the trailing end 26 of the outer housing 22 or the distal end 16 of the handle 12. The connecting element 30 can optionally be adapted to allow the size of the circumferential ablation element 20 to be adjusted once positioned around the pulmonary veins. For example, the connecting element 30 can be positioned around the trailing end 26 of the outer housing 22 after the circumferential ablation element 20 is looped around the pulmonary veins, and the handle 12 can then be pulled to cause the ablation element 20 to tighten around the pulmonary veins. While FIG. 1A illustrates a U-shaped connecting element, a person having ordinary skill in the art will appreciate that a variety of different connecting elements or clasps 30 can be used such as, for example, a hook, a cord, a snap, or other similar connecting device.

The light delivering element 32 which is disposed within the outer housing 22 includes a light transmitting optical fiber 34 and a light diffusing tip 36. The light transmitting optical fiber 34 is effective for delivering radiant energy from the laser energy source 50 to the light diffusing tip 36, wherein the laser energy is diffused throughout the tip 36 and delivered to the target ablation site. The light delivering element 32 can be slidably disposed within the outer housing to allow the light diffusing tip 36 to be positioned with respect to the target ablation site. A lever 52 or similar mechanism can be provided for slidably moving the light delivering element 32 with respect to the handle 12. As shown in FIG. 1A, the lever 52 can be mated to the light delivering element 32 and can protrude from a distally extending slot 54 formed in the

handle 12. Markings can also be provided on the handle for determining the distance moved and the length of the lesion formed. A person having ordinary skill in the art will readily appreciate that a variety of different mechanisms can be employed to slidably move the light delivering element 32 with respect to the handle 12.

Another embodiment of the surgical ablation instrument 10A is shown in FIG. 2, where a rotatable lever 82 can be used to control the positioning of a light delivery element in the distal tip of the instrument. The lever 82 turns a translatory mechanism 80, as shown in more detail in FIG. 2A. In this embodiment, a portion 84 of the handle is separated from the rest of the housing 88 such that it can rotate, and preferably sealed by O-rings 90 and 91, or the like. The rotatable segment 84 has internal screw threads 92. Within this segment of the handle, the light delivering fiber 32 is joined to a jacket 93 that has an external screw thread 94. The threads 94 of jacket 93 mate with the threads 92 of rotatable segment 84. The lever 82 is affixed to rotatable segment 84 (e.g., by set screw 86) such that rotation of knob 82 causes longitudinal movement of the fiber 32 relative to the housing 88.

The inner lumen of the outer housing 22 in FIGS. 1 and 2 can optionally contain a lubricating and/or irrigating fluid to assist the light delivering element 32 as it is slidably movable within the outer housing 22. The fluid can also cool the light delivering element 32 during delivery of ablative energy. Fluid can be introduced using techniques known in the art, but is preferably introduced through a port and lumen formed in the handle. The distal end 24 of the outer housing 22 can include a fluid outflow port 28 for allowing fluid to flow therethrough.

As shown in FIG. 3, the fluid travels between the light delivering element 32 toward the leading, distal end 26 of the outer housing 22 and exits the fluid outflow port 28. Since the port 28 is positioned on the distal end 26 of the outer housing 22, the fluid does not interfere with the ablation procedure. Suitable cooling and/or lubricating fluids include, for example, water and silicone. While FIG. 3 illustrates the fluid outflow port 28 disposed on the distal end 24 of the outer housing 22, a person having ordinary skill in the art will readily appreciate that the fluid outflow port 28 can be disposed anywhere along the length of the outer housing 22.

In FIG 3A another embodiment of a light delivery element according to the invention is shown in fiber 34 terminates in a series of partially reflective elements 35A – 35G. (It should be appreciated that the number of reflective elements can vary depending on the application and the choice of six is merely for illustration.) The transmissivity of the various segments can controlled such that, for example, segment 35A is less reflective than segment 35B, which in turn is less reflective than 35C, etc., in order to achieve uniform diffusion of the light. The reflective elements of FIG. 3A can also be replaced, or augmented, by a series of light scattering elements having similar progressive properties. FIG. 3A also illustrates another arrangement of exit ports 28 in housing 22 for fluid, whereby the fluid can be used to irrigate the target site.

With reference again to FIG 3, the light transmitting optical fiber 34 generally includes an optically transmissive core surrounded by a cladding and a buffer coating (not shown). The optical fiber 34 should be flexible to allow the fiber 34 to be slidably moved with respect to the handle 12. In use, the light transmitting optical fiber 34 conducts light energy in the form of ultraviolet light, infrared radiation, or coherent light, e.g., laser light. The fiber 34 can be formed from glass, quartz, polymeric materials, or other similar materials which conduct light energy.

The light diffusing tip 36 extends distally from the optical fiber 34 and is formed from a transmissive tube 38 having a light scattering medium 40 disposed therein. For additional details on construction of light diffusing elements, see, for example, U.S. Patent 5,908,415 issued June 1, 1999.

The scattering medium 40 disposed within the light diffusing tip 36 can be formed from a variety of materials, and preferably includes light scattering particles. The refractive index of the scattering medium 40 is preferably greater than the refractive index of the housing 22. In use, light propagating through the optical fiber 34 is transmitted through the light diffusing tip 36 into the scattering medium 40. The light is scattered in a cylindrical pattern along the length of the light diffusing tip 36 and, each time the light encounters a scattering particle, it is deflected. At some point, the net deflection exceeds the critical angle for internal reflection at the interface between the housing 22 and the scattering medium 40, and the light exits the housing 22 to ablate the tissue.

Preferred scattering medium 40 includes polymeric material, such as silicone, epoxy, or other suitable liquids. The light scattering particles can be formed from, for example, alumina, silica, or titania compounds, or mixtures thereof. Preferably, the light diffusing tip 36 is completely filled with the scattering medium 40 to avoid entrapment of air bubbles.

As shown in more detail in FIG. 3, the light diffusing tip 36 can optionally include a reflective end 42 and/or a reflective coating 44 extending along a length of one side of the light diffusing tip 36 such that the coating is substantially diametrically opposed to the target ablation site. The reflective end 42 and the reflective coating 44 interact to provide a substantially uniform distribution of light throughout the light diffusing tip 36. The reflective end 42 and the reflective coating 44 can be formed from, for example, a mirror or gold coated surface. While FIG. 3 illustrates the coating extending along one side of the length of the diffusing tip 36, a person having ordinary skill in the art will appreciate that the light diffusing tip 36 can be coated at different locations relative to the target ablation site. For example, the reflective coating 44 can be applied over 50% of the entire diameter of the light diffusing tip 36 to concentrate the reflected light toward a particular target tissue site, thereby forming a lesion having a relatively narrow width.

In use, the hand held ablation instrument 10 is coupled to a source of phototherapeutic radiation 50 and positioned within a patient's body either endocardially or epicardially to ablate the tissue. The radiation source is activated to transmit light through the optical fiber 34 to the light diffusing tip 36, wherein the light is scattered in a circular pattern along the length of the tip 36. The tube 38 and the reflective end 42 interact to provide a substantially uniform distribution of light throughout the tip 36. When a mirrored end cap 42 is employed, light propagating through the light diffusing tip 36 will be at least partially scattered before it reaches the mirror 42. When the light reaches the mirror 42, it is then reflected by the mirror 42 and returned through the tip 36. During the second pass, the remaining radiation encounters the scattering medium 40 which provides further diffusion of the light.

When a reflective coating or longitudinally disposed reflector 44 is used, as illustrated in FIG. 4, the light 58 emitted by the diffusing tip 36 will reflected toward the target ablation site 56 to ensure that a uniform lesion 48 is created. The reflective

coating or element 44 is particularly effective to focus or direct the light 58 toward the target ablation site 56, thereby preventing the light 58 from passing through the housing 22 around the entire circumference of the housing 22.

In another embodiment as illustrated in FIG. 4A, the light emitting element can further include a longitudinally extended lens element 45, such that light scattered by the scattering medium 40 is not only reflected by reflector 44 but also confined to a narrow angle.

In yet another embodiment of the invention, illustrated in FIG. 4B, the housing 22 that surrounds the light delivery element that include or surround a malleable element 47, e.g., a soft metal bar or strip such that the clinician can form the distal end of the instrument into a desired shape prior to use. Although the malleable element 47 is shown embedded in the housing 22, it should be clear that it can also be incorporated into the light delivery element (e.g., as part of the longitudinally extended reflector) or be distinct from both the housing and the light emitter.

Epicardial ablation is typically performed during a by-pass procedure, which involves opening the patient's chest cavity to access the heart. The heart can be arrested and placed on a by-pass machine, or the procedure can be performed on a beating heart. The hand held ablation instrument 10 is placed around one or more pulmonary veins, and is preferably placed around all four pulmonary veins. The connecting element 30 can then be attached to the distal end 16 of the handle 12 or the proximal, trailing end 24 of the outer housing 22 to close the open loop. The handle 12 can optionally be pulled to tighten the ablation element 20 around the pulmonary veins. The light delivering element 32 is then moved to a first position, as shown in FIG. 5, and the laser energy source 50 is activated to transmit light. The first lesion is preferably about 4 cm in length, as determined by the length of the light diffusing tip 36. Since the distance around the pulmonary veins is about 10 cm, the light delivering element 32 is moved forward about 4 cm to a second position 60, shown in phantom in FIG. 5, and the tissue is ablated to create a second lesion. The procedure is repeated two more times, positioning the light delivering element 32 in a third position 62 and a fourth position 64. The four lesions together can form a lesion 48 around the pulmonary veins, for example.

In another aspect of the invention, the instruments of the present invention are particularly useful in forming lesions around the pulmonary veins by directing radiation towards the epicardial surface of the heart and the loop configuration of distal end portion of the instruments facilitates such use. It has been known for some time that pulmonary veins can be the source of errant electrical signals and various clinicians have proposed forming conduction blocks by encircling one or more of the pulmonary veins with lesions. As shown in FIG. 6, the instrument 10 of the present invention is well suited for such ablation procedures. Because the pulmonary veins are located at the anterior of the heart muscle, they are difficult to access, even during open chest surgery. An open loop distal end is thus provided to encircle the pulmonary veins. The open loop can then be closed (or cinched tight) by a clasp, as shown. (The clasp can also take the form of suture and the distal end of the instrument can include one or more holes to receive such sutures as shown in FIG. 2.) The longitudinal reflector structures described above also facilitate such epicardial procedures by ensuring that the light from the light emitting element is directed towards the heart and not towards the lungs or other adjacent structures.

Endocardial applications, on the other hand, are typically performed during a valve replacement procedure which involves opening the chest to expose the heart muscle. The valve is first removed, and then the hand held cardiac ablation instrument 10 according to the present invention is positioned inside the heart as shown in FIG 7. In another approach the instrument 10 can be inserted through an access port as shown in FIG. 8. The ablation element 20 can be shaped to form the desired lesion, and then positioned at the atrial wall around the ostia of one or more of the pulmonary veins. Once shaped and positioned, the laser energy source 50 is activated to ablate a first portion of tissue. The light delivering element 32 can then be slidably moved, as described above with respect to the epicardial application, or alternatively, the entire device can be rotated to a second position to form a second lesion.

Preferred energy sources for use with the hand held cardiac ablation instrument 10 of the present invention include laser light in the range between about 200 nanometers and 2.5 micrometers. In particular, wavelengths that correspond to, or are near, water absorption peaks are often preferred. Such wavelengths include those between about 805 nm and about 1060 nm, preferably between about 900 nm and 1000

nm, most preferably, between about 940 nm and 980 nm. Suitable lasers include excimer lasers, gas lasers, solid state lasers and laser diodes. One preferred AlGaAs diode array, manufactured by Optopower, Tucson, Arizona, produces a wavelength of 980 nm. Typically the light diffusing element emits between about 2 to about 10 watts/cm of length, preferably between about 3 to about 6 watts/cm, most preferably about 4 watts/cm.

The term "curvilinear," including derivatives thereof, is herein intended to mean a path or line which forms an outer border or perimeter that either partially or completely surrounds a region of tissue, or separate one region of tissue from another. Further, a "circumferential" path or element may include one or more of several shapes, and may be for example, circular, annular, oblong, ovular, elliptical, or toroidal. The term "clasp" is intended to encompass various types of fastening mechanisms including sutures and magnetic connectors as well as mechanical devices. The term "light" is intended to encompass radiant energy, whether or not visible, including ultraviolet, visible and infrared radiation.

One skilled in the art will appreciate further features and advantages of the invention based on the above-described embodiments. Accordingly, the invention is not to be limited by what has been particularly shown and described, except as indicated by the appended claims. All publications and references cited herein are expressly incorporated herein by reference in their entirety.

What is claimed is:

1. A surgical ablation instrument comprising

a housing having at least one lumen therein and having a distal portion that is at least partially transmissive to photoablative light; and

a light delivery element disposable within the lumen of the housing and adapted to receive light from a light source and to delivery radiant energy through a transmissive region of the housing to a target tissue site.

2. The instrument of claim 1, wherein the light delivering element further comprises a light transmitting optical fiber adapted to receive ablative light from a light source and a light emitting tip at a distal end of the fiber for emitting diffuse or defocused light.

3. The instrument of claim 2, wherein the light transmitting optical fiber is capable of transmitting light of at least one wavelength in a range from about 800 nm to about 1000 nm, and preferably of at least one wavelength in a range of about 915 nm to about 980 nm.

4. The ablation instrument of claim 1 wherein the housing has a curved distal portion with at least one lumen therein and the light delivering element is disposable within the lumen of the curved portion for delivering ablative light to form a curvilinear lesion at a target tissue site adjacent to the housing.

5. The instrument of claim 1, wherein the light delivering element is slidably disposed within the inner lumen of the housing and the instrument further comprises a translatory mechanism for disposing the tip of the light delivering element at one or more of a plurality of locations with the housing and, optionally, a lubricating fluid is disposable between the light delivery element and the housing.

6. The instrument of claim 2, wherein the light emitting tip comprises:

a hollow tube having a proximal end joined to the light transmitting optical fiber, a closed distal end, and an inner space defining a chamber therebetween; and

a light scattering medium disposed within the chamber to distribute light propagating through the fiber through the transmissive region of the housing toward a target site in an elongated pattern,

the light scattering medium, optionally, comprising a polymeric or liquid material having light scattering particles incorporated therein.

7. The instrument of claim 6, wherein the light scattering medium comprises light scattering particles and has a refractive index greater than a refractive index of the housing and, optionally, wherein the light scattering particles are chosen from the group consisting of alumina, silica, and titania compounds and mixtures thereof.

8. The instrument of claim 7, wherein the distal end of the tube includes a reflective end and, optionally, the scattering medium and the reflective end interact to provide a substantially uniform axial distribution of light over the length of the housing.

9. The instrument of claim 2 wherein the light emitting tip further comprises at least one reflector for directing the light through the transmissive region of the housing toward a target site and, optionally further comprises a plurality of reflectors and/or at least one defocusing lens for distributing the light in an elongated pattern.

10. The instrument of claim 2 wherein the light emitting tip further comprises at least one longitudinal optical element such that the light distributed by the tip is confined to desired angular distribution.

11. The instrument of claim 1, wherein the distal portion of the instrument has a malleable shape or is in the shape of an open loop so as to allow the loop to be placed around at least one a pulmonary vein or artery and, optionally, the distal portion of housing can be shaped into a loop having a diameter between about 10 and 50 mm.

12. The instrument of claim 11 wherein the instrument further comprises at least one malleable strip element disposed at the distal portion of the housing.

13. The instrument of claim 1, wherein the instrument further comprises a light source for generating photoablative radiation at a desired wavelength ranging from about 800 nm to about 1000 nm, and optionally ranging from about 915 nm to about 980 nm.

14. The instrument of claim 1, wherein the instrument further comprises a light source for generating photoablative radiation at a wavelength of about 915 nm.

15. A method of ablating cardiac tissue, comprising:

positioning a distal portion of a photoablation instrument in proximity to a target region of cardiac tissue, the instrument having a hollow housing and a light delivering element coupled to a source of photoablative radiation and disposed within the distal portion, the distal portion being transmissive to a selected wavelength of ablative radiation and curved to permit the distribution of radiation by the light emitting element in an elongated arcuate pattern;

activating the light emitting element to transmit radiant energy through the housing to expose the target region and induce an curvilinear lesion; and, optionally,

repeating the steps of positioning and exposing until a composite lesion of a desired shape is formed

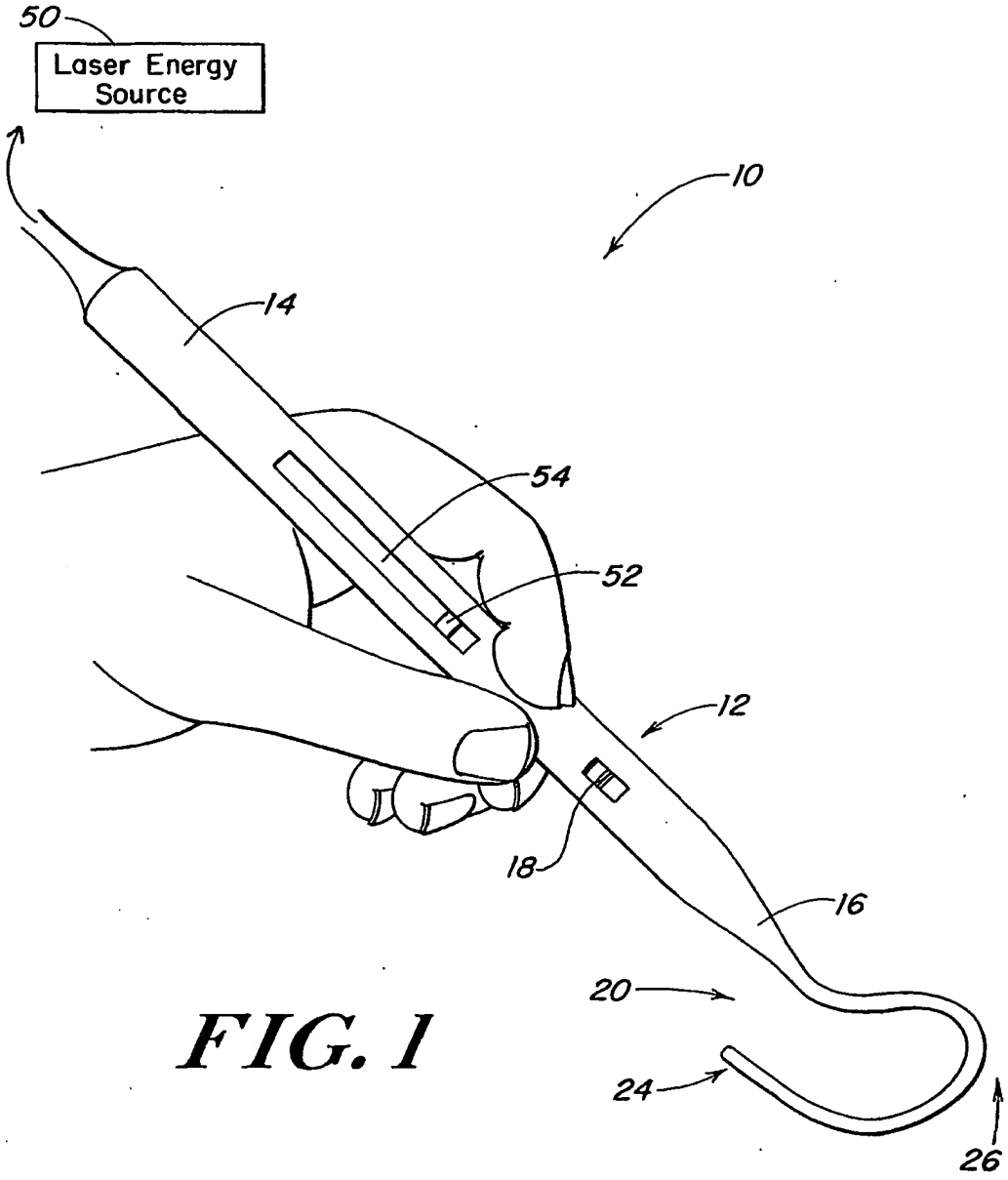

FIG. 1

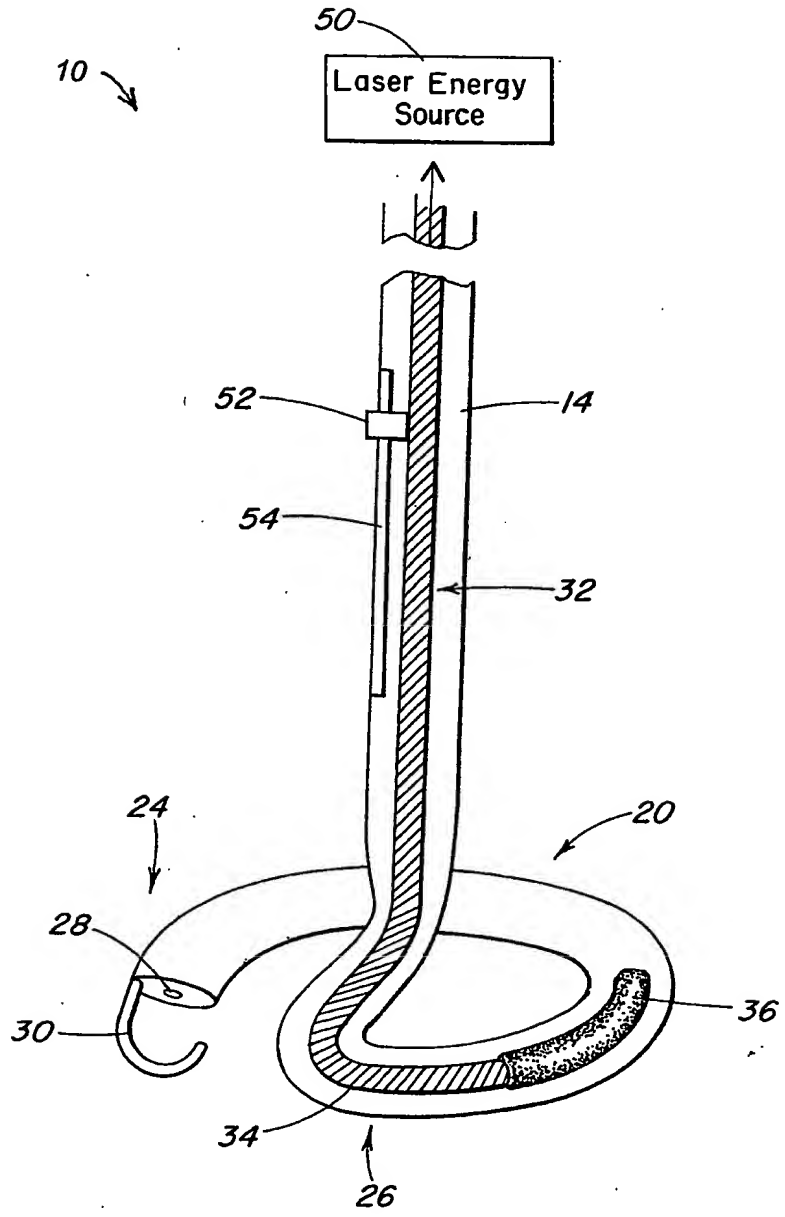

FIG. 1A

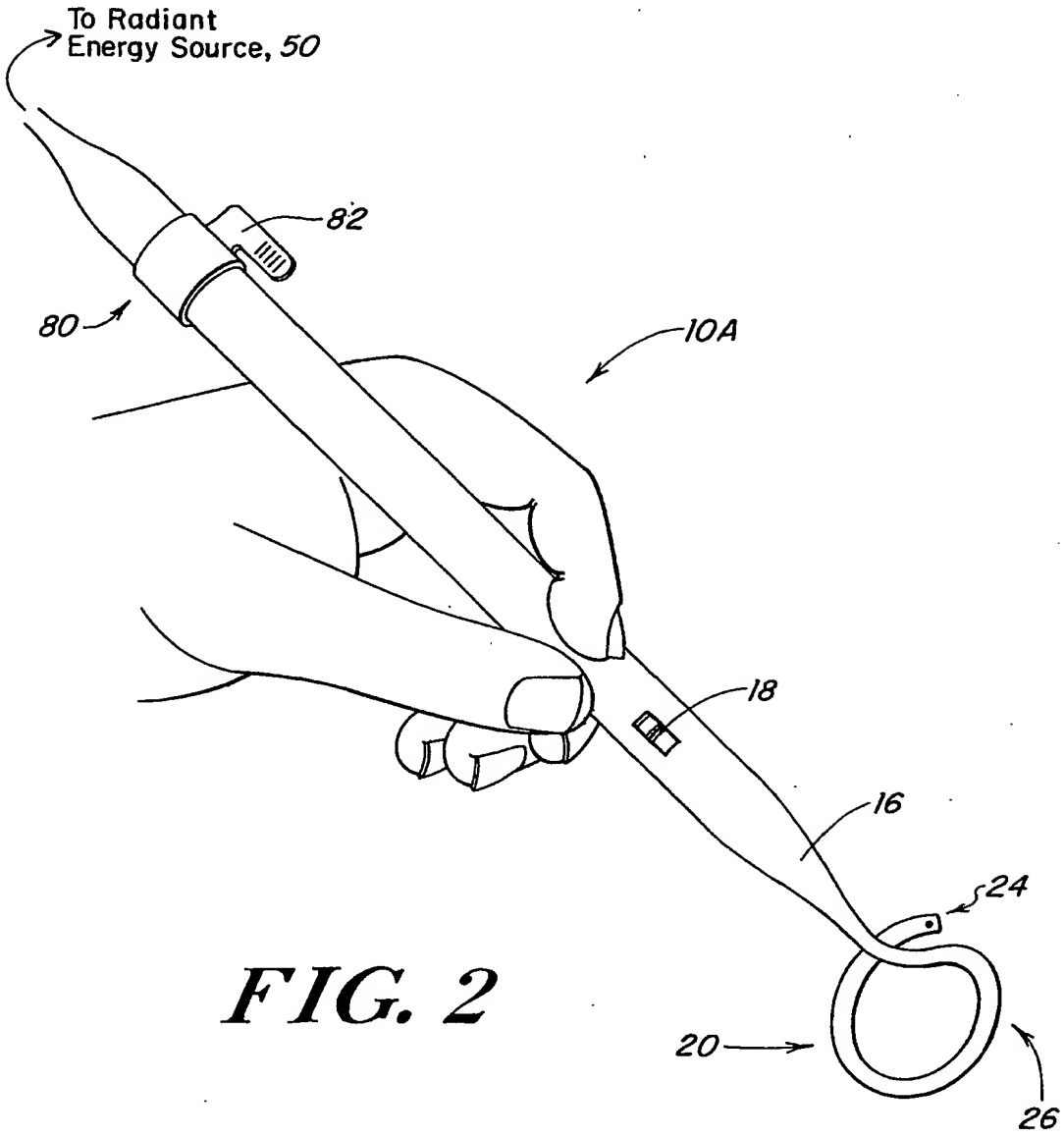

FIG. 2

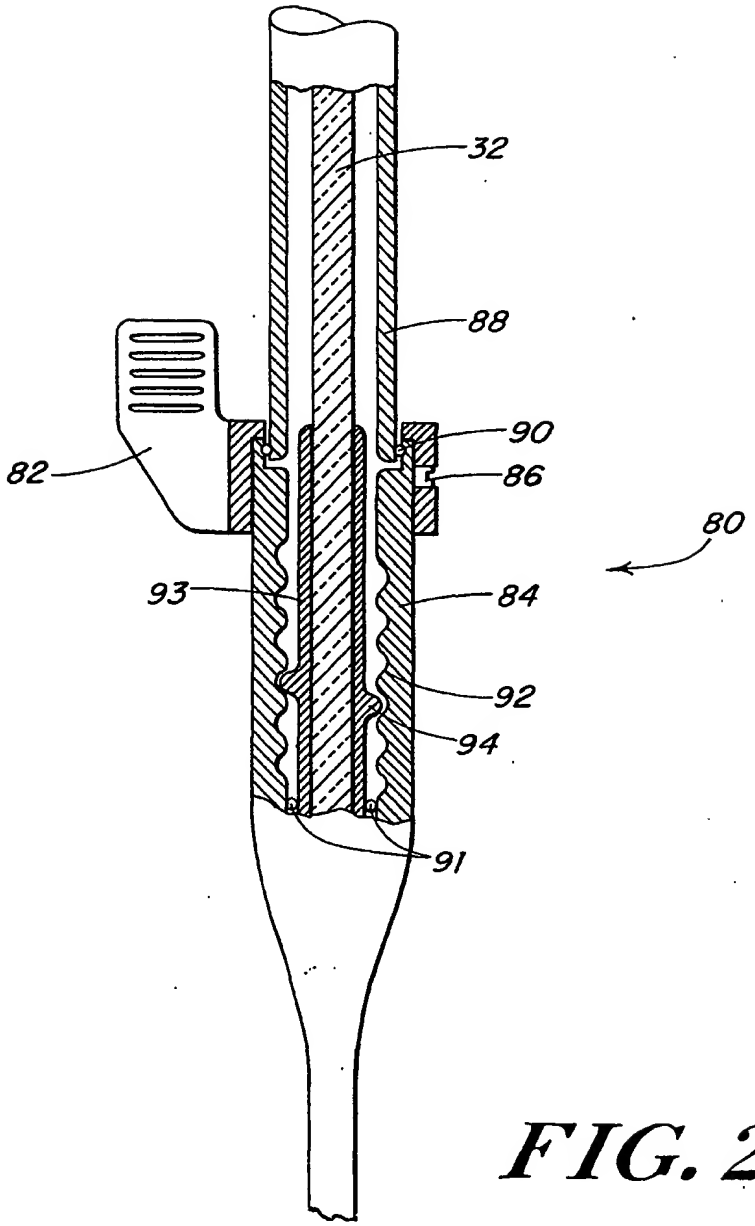

FIG. 2A

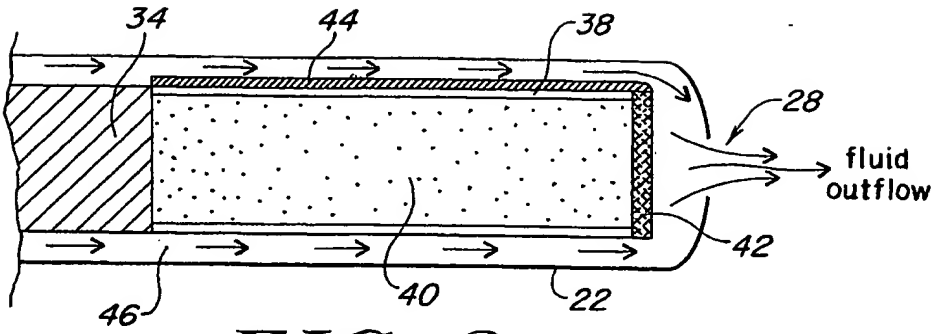

FIG. 3

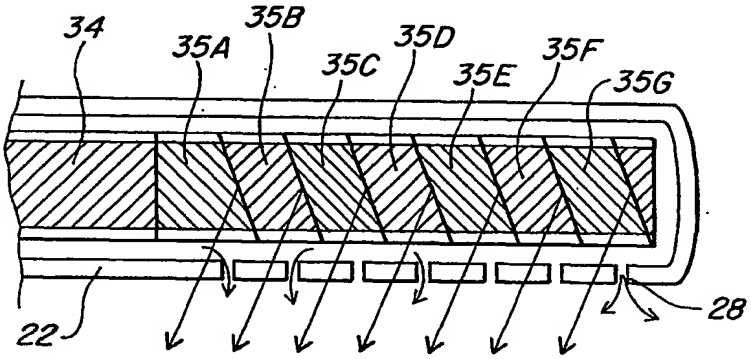

FIG. 3A

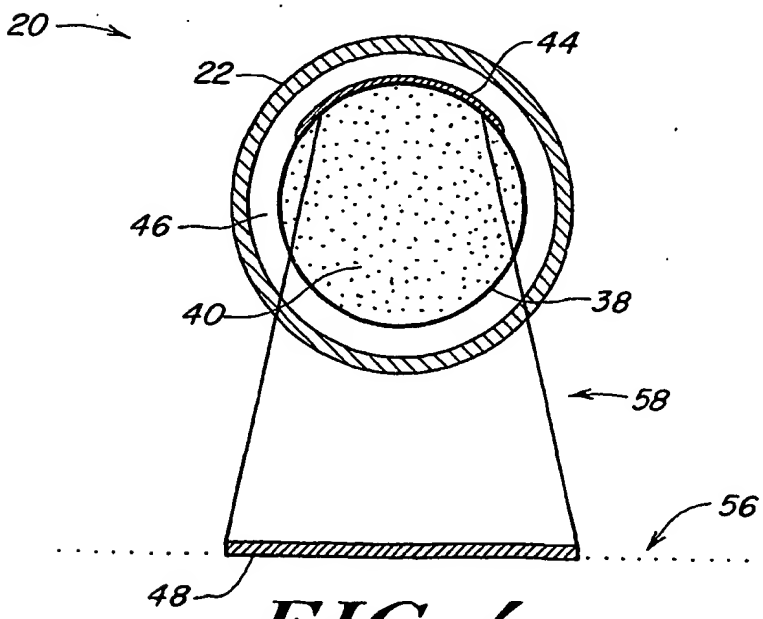

FIG. 4

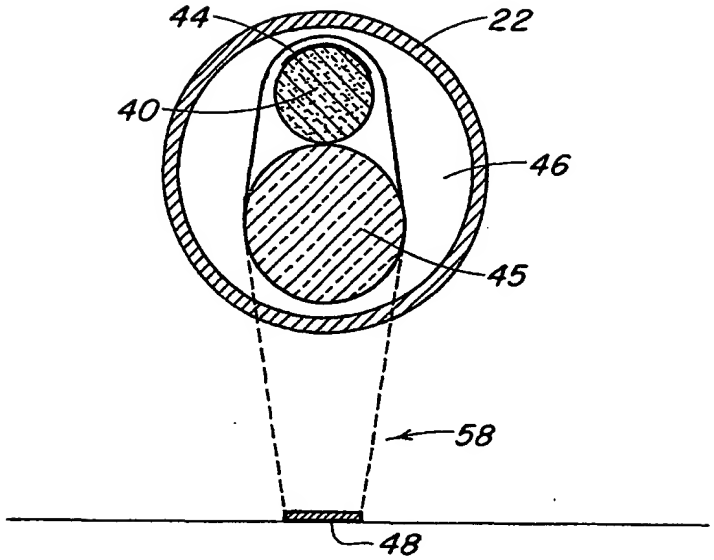

FIG. 4A

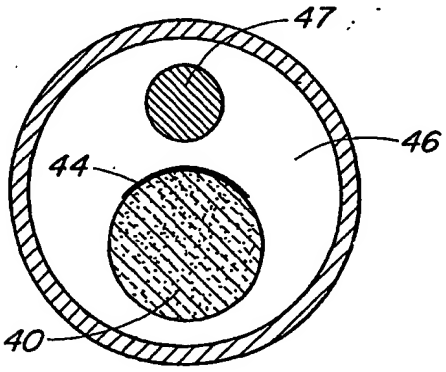

FIG. 4B

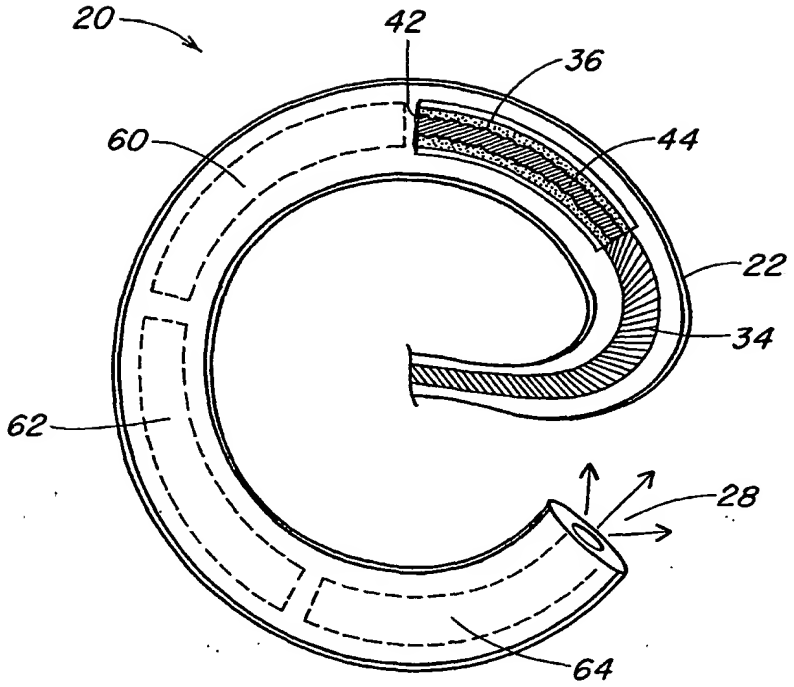

FIG. 5

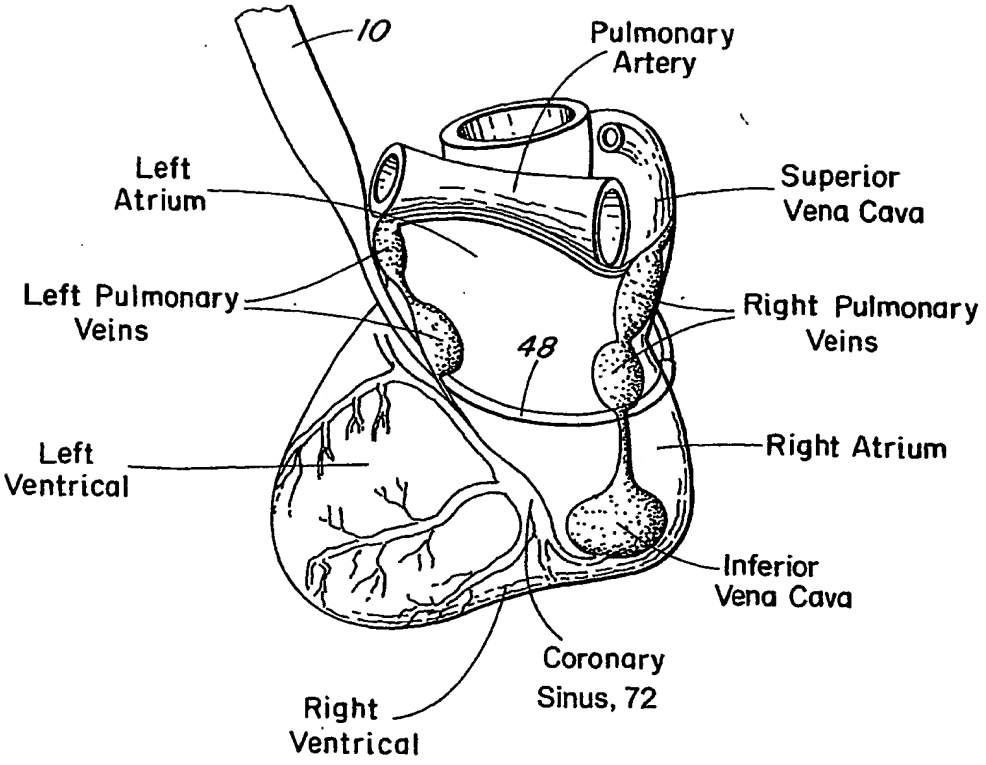
10
Pulmonary Artery
Left Atrium
Superior Vena Cava
Left Pulmonary Veins
Right Pulmonary Veins
48
Left Ventrical
Right Atrium
Inferior Vena Cava
Coronary Sinus, 72
Right Ventrical

FIG. 6

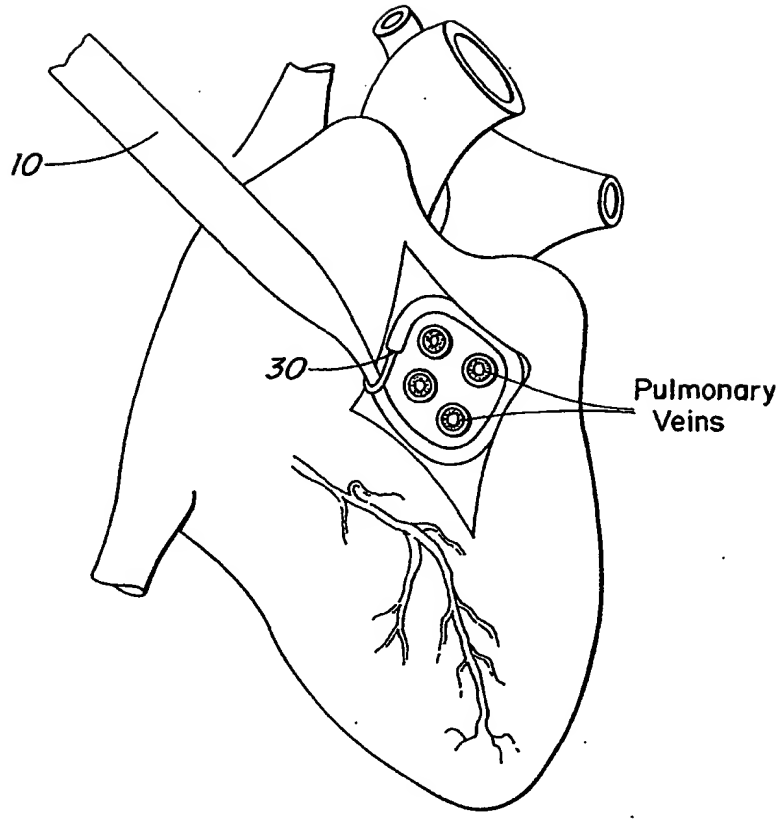

FIG. 7

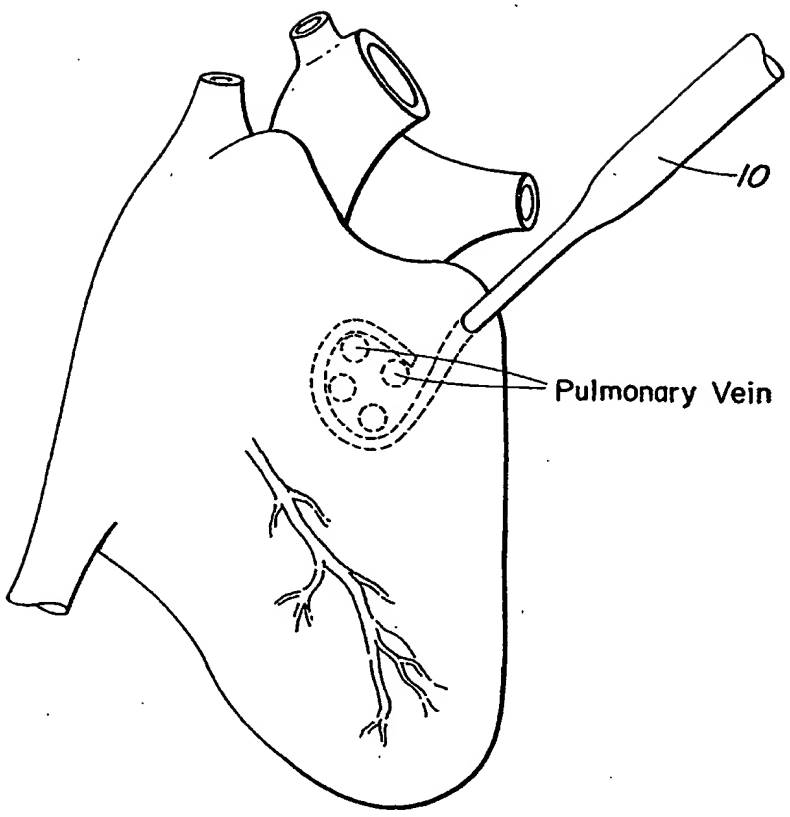

FIG. 8

INTERNATIONAL SEARCH REPORT

In ional Application No
PCT/US 01/22299

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B18/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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A	page 10, line 31 - line 36; figure 1 page 15, line 17 - line 22; figure 13 page 16, line 33 - line 37; figure 18	3,5,13, 14
X	WO 94 26184 A (BEUTHAN JUERGEN ;MUELLER GERHARD (DE); ROGGAN ANDRE (DE); BERLIN L) 24 November 1994 (1994-11-24) page 9, line 18 - line 24 page 18, line 10 -page 19, line 8; figure 4	1-3,10, 13

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
6 November 2001	13/11/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mayer, E

INTERNATIONAL SEARCH REPORT

Int[illegible] onal Application No
PCT/US 01/22299

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

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X	US 5 649 923 A (ANDERSON R ROX ET AL) 22 July 1997 (1997-07-22) column 11, line 54 -column 12, line 18; figure 16	1,2,5
A	DE 94 11 754 U (GOEBEL DIETER DR) 10 November 1994 (1994-11-10) page 8, line 29 -page 9, line 12; figure 2	1,4
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P,X	EP 1 072 231 A (TERUMO CORP) 31 January 2001 (2001-01-31) column 17, line 44 -column 18, line 16; figure 22	1,4,5, 13,14

INTERNATIONAL SEARCH REPORT

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